



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0369]

Product-Specific Guidances for Ferric Oxyhydroxide; Revised Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of revised draft guidances for industry entitled “Draft Guidance for Ferric Oxyhydroxide.” The revised draft guidances, when finalized, will provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for ferric oxyhydroxide oral tablets (previously sucroferric oxyhydroxide) and ferric oxyhydroxide intravenous injectable (previously iron sucrose).

DATES: Submit either electronic or written comments on the draft guidances by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** to ensure that the Agency considers your comment on these draft guidances before it begins work on the final versions of the guidances.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment

does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2007-D-0369 for "Draft Guidance for Ferric Oxyhydroxide." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT

CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Christine Le, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4714, Silver Spring, MD 20993-0002, 301-796-2398 and/or PSG-Questions@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled “Bioequivalence Recommendations for Specific Products,” which explained the process that would be used to make product-specific guidances available to the public on FDA’s website at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>.

As described in that guidance, FDA adopted this process to develop and disseminate product-specific guidances and to provide a meaningful opportunity for the public to consider and comment on the guidances. This notice announces the availability of revised draft guidances on ferric oxyhydroxide oral tablets and ferric oxyhydroxide intravenous injectable.

FDA initially approved new drug application (NDA) 205109 VELPHORO in November 2013 and NDA 021135 VENOFER in November 2000.¹ In March 2015, FDA issued a draft product specific guidance for industry on generic ferric oxyhydroxide oral tablets (previously entitled “Draft Guidance for Sucroferric Oxyhydroxide”) and in November 2013, FDA issued a draft product specific guidance for industry on generic ferric oxyhydroxide intravenous injectable (previously entitled “Draft Guidance for Iron Sucrose”). We are now issuing revised draft guidances for industry on generic ferric oxyhydroxide oral tablets and ferric oxyhydroxide intravenous injectable.

In August 2021, Sidley Austin LLP submitted a citizen petition requesting that FDA take several actions, including refraining from changing the product label or labeling for VENOFER,

¹ The active ingredients were previously identified as sucroferric oxyhydroxide and iron sucrose, respectively, at the time of approval of these NDAs. FDA later concluded that the active ingredient in both of these products is ferric oxyhydroxide. See Letter to Areta Kupchyk, Foley Hoag LLP, from Patrizia Cavazzoni, M.D., Acting Director, Center for Drug Evaluation and Research, Docket No. 2016-P-1163 (May 26, 2021).

any action to modify the existing product-specific guidance for VENOFER, and any action to change the established name of VENOFER to ferric oxyhydroxide (Docket No. FDA-2021-P-0893). FDA is reviewing the issues raised in the petition and will consider any comments on the draft guidances entitled “Draft Guidance for Ferric Oxyhydroxide” before responding to the petition. FDA’s issuance of the draft guidances on generic ferric oxyhydroxide oral tablets and ferric oxyhydroxide intravenous injectable does not represent a final decision on the issues raised in the petition.

The revised draft guidances are being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The revised draft guidances, when finalized, will represent the current thinking of FDA on the design of BE studies to support ANDAs for ferric oxyhydroxide. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: September 13, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.